

Notice of Agency Rule-making Proposal

AGENCY: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Board of Pharmacy

CHAPTER NUMBER AND TITLE: Chapter 34-A: Licensure of Retail Suppliers of Prescription Medical Devices (new)

PROPOSED RULE NUMBER (*leave blank; assigned by Secretary of State*):

CONTACT PERSON FOR THIS FILING: Geraldine Betts, Board Administrator, 35 State House Station, Augusta, ME 04333, tel. (207) 624-8625, email geraldine.l.betts@maine.gov

CONTACT PERSON FOR SMALL BUSINESS INFORMATION (if different): Same as above.

PUBLIC HEARING (if any): April 2, 2015 at 8:00 a.m., Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, Maine

COMMENT DEADLINE: April 13, 2015 at 5:00 p.m.

BRIEF *SUMMARY: In this rulemaking, the board proposes a new rule chapter that would require retail suppliers of prescription medical devices to apply for and obtain a new type of limited retail pharmacy license from the board. In 2011, under Chapter 34, the board proposed a limited retail pharmacy license for suppliers of prescription medical devices and a limited retail pharmacy license for suppliers of medical oxygen. The proposal pertaining to suppliers of prescription medical devices was not adopted for various reasons due to public comments received by the board. Since 2011, the board has received a number of requests from suppliers of prescription medical devices for a limited retail pharmacy license similar to the one for medical oxygen suppliers. The board proposes Chapter 34-A in order to meet that request and to provide a more business-friendly resolution to licensing retail suppliers of prescription medical devices. The proposed rule describes and establishes the following: (1) the application process and licensing requirements; (2) a provision for applicants filing an incomplete application to obtain a temporary license to bring their application filing to completeness; (3) the requirement of prescriptions for medical devices; (4) patient recordkeeping requirements; (5) requirements for registering and labeling devices; and (6) an exemption provision for ophthalmologic and ophthalmic aid prescription devices. The proposed rule does not require licensees to hire a pharmacist-in-charge.

The proposed rule may be downloaded from OPOR's web site at www.maine.gov/professionallicensing or obtained from the agency contact person. The statement of economic impact on small business required by 5 MRS § 8052(5-A) may also be obtained from the agency contact person.

IMPACT ON MUNICIPALITIES OR COUNTIES (if any): None

STATUTORY AUTHORITY FOR THIS RULE: 32 MRS §§ 13720, 13721(1)(E), 13722(1)(A), (B) and (C), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different): None

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: holly.doherty@maine.gov

* Check one of the following two boxes.

☒ The above summary is for use in both the newspaper and website notices.

☐ The above summary is for the newspaper notice only. A more detailed summary / basis statement is attached.

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT _____ DATE: _____
(authorized signature)

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 34-A: LICENSURE OF RETAIL SUPPLIERS OF PRESCRIPTION MEDICAL DEVICES

Summary: This chapter provides for the licensure of retail suppliers of prescription medical devices.

1. Authority

A retail supplier of prescription medical devices is a classification of retail pharmacy regulated by the board pursuant to 32 MRS § 13751(2)(A) and § 13751(3).

2. License Required

1. General Requirement

Medical devices requiring a prescription from a practitioner for use by a specific person may be sold at retail. A retail supplier of prescription medical devices located within or outside Maine who sells, rents or dispenses a prescription medical device to consumers who reside in Maine shall obtain a retail supplier of prescription medical device license from the board. A retail supplier of prescription medical devices need not have a pharmacist in charge or a pharmacist.

2. Exception for Licensed Pharmacies

A pharmacy licensed by the board may sell prescription medical devices at retail without need of a license under this chapter.

3. Exception for Ophthalmologic or Ophthalmic Aid Prescription Devices

This chapter is not intended to regulate nor does it apply to Optometrists regulated pursuant to Title 32, Chapter 34-A, or other prescribers or dispensers of ophthalmologic or ophthalmic aid prescription devices, including but not limited to ophthalmic lenses, devices containing lenses, prisms, orthoptics, prosthetic devices, contact lenses, glasses, eye patches or other ophthalmologic aids, ophthalmic or optical aids.

4. Sales for Emergency Medical Use – Dual Licensure Not Required

A retail supplier of prescription medical devices licensed under this chapter who sells devices for emergency medical use to a licensed practitioner or licensed health care facility need not, by virtue of those sales alone, be licensed as a wholesaler pursuant to Chapter 12 of the board's rules.

3. Temporary Licensure

1. Timeline

The board may issue a temporary license as a retail supplier of prescription medical devices upon receipt of an application for licensure submitted pursuant to Section 4 of this chapter. The application must demonstrate the applicant's prima facie eligibility for licensure. The temporary license expires 90 days from the date of issuance. Within the first 60 days of temporary licensure, a temporary licensee shall complete the application to the satisfaction of the board. The board will act on timely-completed applications for licensure within the 90-day period of the temporary license.

2. Limitation

A temporary license may not be extended or renewed. A person may not receive a temporary license more than once per facility location.

4. Licensure

1. Application; Fees

An application for licensure as a retail supplier of prescription medical devices must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Except as described in Section 3 of this chapter, incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, physical address, contact address, telephone number, email address and world wide web address of the retail supplier of prescription medical devices;
- B. All trade or business names used by the retail supplier of prescription medical devices;
- C. The names of the owner of the retail supplier of prescription medical devices, including:
 - (a) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner.
 - (b) If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each

shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State.

- (c) If the applicant is a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
 - (d) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity.
- D. The job title, name, address, telephone number, email address and emergency contact information of the person responsible for operation of the retail supplier of prescription medical devices;
- E. The days and hours of operation of the retail supplier of prescription medical devices;
- F. A scaled drawing of the facility demonstrating sufficient space for the proper carrying on of the business of a retail supplier of prescription medical devices. The drawing must identify the use of all space within the facility;
- G. Such other information as the board may require.

2. **Processing of Application**

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the retail supplier of prescription medical devices will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

3. **Response by Applicant to Adverse Board Action**

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

4. **Separate License for Each Facility**

The owner of a retail supplier of prescription medical devices must file a separate application for each facility that sells or dispenses prescription medical devices.

5. **License Term; Renewal**

All retail supplier of prescription medical devices licenses other than the temporary license expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

6. **Change of Ownership, Location or Application Information**

Upon a change of ownership, a retail supplier of prescription medical devices shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a retail supplier of prescription medical devices shall file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

5. **Prescription Medical Device Order**

Each retail sale or rental of a prescription medical device must be authorized by a prescription from a practitioner. A retail supplier of prescription medical devices may fill a

prescription for the length of medical need authorized by the prescribing practitioner. If the length of medical need is not specified, the prescription device order is valid for 15 months.

6. Patient Records

A retail supplier of prescription medical devices shall keep in written or any electronic format prescriptions, invoices and delivery records for each patient served. Records must be retained for 3 years from the date of last delivery to a patient and must be produced to an inspector or representative of the board upon request.

7. Labeling

1. Requirements

A retail supplier of prescription medical devices shall comply with the labeling requirements promulgated by the Food and Drug Administration in 21 CFR Part 801 “Labeling” (Revised April 1, 2014), available online. The board hereby incorporates this document by reference into this chapter:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

2. Exemption

The requirements set forth in 32 MRS § 13784 do not apply to a retail supplier of prescription medical devices licensed under this chapter.

8. Registration

A retail supplier of prescription medical devices that engages in medical device manufacturing, production, or distribution, as defined in the Federal Food, Drug, and Cosmetic Act and its implementing rules, shall comply with the registration requirements promulgated by the Food and Drug Administration in 21 CFR Part 807 “Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices” (Revised April 1, 2014), available online. The board hereby incorporates this document by reference into this chapter:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

9. Current Good Manufacturing Practices

A retail supplier of prescription medical devices that engages in medical device manufacturing, as defined in the Federal Food, Drug, and Cosmetic Act and its implementing rules, shall comply with the current good manufacturing practices promulgated by the Food and Drug Administration in 21 CFR Part 820 “Quality System Regulation” (Revised April 1,

2014), available online. The board hereby incorporates this document by reference into this chapter:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13722(1)(A), (B) and (C), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

Rule-Making Fact Sheet

(5 MRS § 8057-A)

AGENCY: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Board of Pharmacy

NAME, ADDRESS, PHONE NUMBER OF AGENCY CONTACT PERSON: Geraldine Betts, Board Administrator, 35 State House Station, Augusta, ME 04333, tel. (207) 624-8625, email geraldine.l.betts@maine.gov

CHAPTER NUMBER AND RULE TITLE: Chapter 34-A: Licensure of Retail Suppliers of Prescription Medical Devices

STATUTORY AUTHORITY: 32 MRS §§ 13720, 13721(1)(E), 13722(1)(A), (B) and (C), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

DATE AND PLACE OF PUBLIC HEARING: April 2, 2015 at 8:00 a.m., Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, Maine

COMMENT DEADLINE: April 13, 2015 at 5:00 p.m.

PRINCIPAL REASON OR PURPOSE FOR PROPOSING THIS RULE: Under the board's current rules, entities that dispense and sell prescription medical devices must be licensed as retail pharmacies. Many of the requirements for licensure as a retail pharmacy are unduly burdensome for these entities and require a pharmacist-in-charge. The proposed rule creates a new type of limited retail pharmacy license that is more appropriately tailored to these entities.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (PRIMARY SOURCES): The Maine Pharmacy Act at 32 M.R.S. §§ 13701 - 13847, Board Rule Chapter 34 pertaining to the operation of entities that dispense prescription medical oxygen and oxygen devices, and other related Board rules.

Also, the Federal Food, Drug, and Cosmetic Act and its implementation of the following regulations: (1) 21 CFR Part 801 "Labeling" (Revised April 1, 2014); (2) 21 CFR Part 807 "Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices" (Revised April 1, 2014); and (3) 21 CFR Part 820 "Quality System Regulation" (Revised April 1, 2014).

ANALYSIS AND EXPECTED OPERATION OF THE RULE: The proposed rule would require retail suppliers of prescription medical devices to apply for a limited retail pharmacy license from the board. This licensure is necessary to ensure that prescriptions for medical devices are accurately filled, that records of sale are available to the board in case of an adverse medical event, and that registration and labeling requirements and state laws and rules are complied with.

The license application and processing language has been standardized throughout the rules and has therefore been incorporated into the proposed rule for consistency. For example, the

reporting requirements for change of ownership, location, and application information is the same for retail pharmacies, retail suppliers of medical oxygen, extended hospital pharmacies, opioid treatment programs, sterile compounding pharmacies, and closed-shop pharmacies.

The proposed rule also provides for a period of temporary licensure upon receipt of an application, a provision also present in current Chapter 34, “Licensure of Retail Suppliers of Medical Oxygen.” Temporary licensure allows entities to operate while an application is pending, and is particularly useful in preventing a gap in licensure for those entities currently holding a retail pharmacy license. Gaps in licensure can negatively affect patients by preventing them from getting prescription medical devices in a timely fashion.

FINDINGS UNDER CRITERIA CONTAINED IN EXECUTIVE ORDER 20 FY 11/12:

(A) The proposed rule will not negatively impact job growth or creation; (B) There are no fees included in the rule; (C) There is no cost to the public in terms of time and money required to comply with the rule; (D) The dispensing and selling of prescription medical devices is regulated by the Maine Pharmacy Act; and (E) The dispensing and selling of prescription medical devices is extensively regulated by the federal laws and rules and this chapter is not inconsistent with the federal standards.

FISCAL IMPACT OF THE RULE: None.

FOR RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:

INDIVIDUALS OR GROUPS AFFECTED AND HOW THEY WILL BE AFFECTED:

BENEFITS OF THE RULE: